

Application No.: 09/828,607
Amendment dated April 23, 2004
In response to Examiner's Office Action dated December 23, 2003

REMARKS

Claims 1-27, 30-34, 47, 48, 50 and 57-60 are pending in this application.

Applicants have amended claims 1 and 47 to recite a method for repairing a defect locus in a nonarticular cartilage tissue and promoting chondrogenesis at a nonarticular defect locus, respectively, wherein the formation of functional permanent cartilage tissue is induced. Support for this amendment is provided, for example, at specification page 31, lines 26-28.

None of the amendments adds new matter.

Applicants address the Examiner's rejection below:

35 U.S.C. § 103(a)

Claims 1-25, 30-34, 47-48, 57 and 59-60

The Examiner has maintained the rejection of claims 1-25, 30-34, 47-48, 57 and 59-60 under 35 U.S.C. § 103(a) as being obvious over WO 96/14335 ("Luyten") in view of WO 95/16035 ("Celeste") and Cui et al., "Repair of thyroid cartilage defect

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with bone morphogenetic protein," Annals of Otology, Rhinology and Laryngology, 106, pp. 326-328 (1997) ("Cui"). The Examiner states that Luyten discloses BMP-2, 3, 5 and that BMPs are used for cartilage and bone development. The Examiner states that Celeste teaches BMPs with the same activity as disclosed in Luyten and a pharmaceutical acceptable carrier such as collagen. The Examiner further states that Cui teaches the repair of thyroid cartilage defect with BMPs. The Examiner, therefore, concludes that it would have been obvious to one skilled in the art to arrive at the claimed invention by combining the teachings of the cited references.

First, applicants have amended claims 1 and 47 (and therefore, claims dependent thereon) to recite a method for repairing a defect locus in a nonarticular cartilage tissue and a method for promoting chondrogenesis at a nonarticular defect locus, respectively, using specific osteogenic proteins to induce the formation of functional permanent cartilage tissue. Therefore, the claims of the instant application require that functional replacement cartilage tissue be induced.

Luyten discloses that BMPs may have cartilage and bone inducing activity. However, Luyten discloses this activity in the context of the stages of endochondral bone formation. Specifically, Luyten states that the normal stages of endochondral bone formation "include mesenchymal condensation, cartilage, and bone marrow formation and eventual mineralization to produce mature bone" (see, page 1, lines 25-27). Furthermore, Luyten discloses that BMPs induce bone formation in addition to cartilage formation (see, page 17, lines 34-35). Therefore, in contrast with the amended claims of the instant application, the cartilage formation disclosed in Luyten is not permanent.

Neither Cui nor Celeste remedies this deficiency. Cui discloses that bovine BMP repairs a thyroid cartilage defect by inducing new bone formation which fills the defect in the cartilage. Cui teaches that although both new bone and cartilage formation is observed four weeks following implantation of bBMP at the cartilage defect, eight weeks after implantation, the bone formation had advanced to result in the complete closure of the defect (see, page 326, col. 2, to page 328, col.1). Therefore, Cui confirms the teachings of Luyten that cartilage formation is

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temporary. In fact, the combination of Cui and Luyten teaches away from applicant's invention.

Celeste discloses that BMP-12 and BMP-13, either alone or in combination with other BMPs, induce tendon/ligament-like tissue healing and repair. Celeste discloses that BMP-12 implanted rats showed tendon/ligament-like tissue formation but no cartilage or bone formation, whereas BMP-2 implanted rats showed only the expected cartilage and bone formation. Nothing in Celeste teaches or suggests that the cartilage formation is permanent as is recited in the amended claims.

Accordingly, nothing in the combination of Luyten, Celeste or Cui, teaches a method for repairing nonarticular cartilage tissue or promoting chondrogenesis at a nonarticular defect locus by inducing functional permanent cartilage tissue, as recited in the amended claims of this application. Accordingly, applicants request that the Examiner withdraw this obviousness rejection.

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Claims 1-6, 8-25, 27 and 30-34

The Examiner has maintained the rejection of claims 1-6, 8-25, 27 and 30-34 under 35 U.S.C. § 103(a) as being obvious over Cui in view of Celeste.

As described above, applicants have amended claim 1 (and therefore, claims dependent thereon) to recite a method for repairing a defect locus in a nonarticular cartilage tissue using specific osteogenic proteins, wherein the method induces the formation of functional permanent replacement cartilage tissue.

As discussed above, Cui discloses that bovine BMP induces new bone to fill the defect in the cartilage, not functional permanent cartilage as recited in the amended claims of the instant application. And, nothing in Celeste provides any teaching or suggestion that the recited osteogenic proteins claimed in the instant application are capable of inducing permanent replacement cartilage tissue.

Thus, nothing in the combination of Cui or Celeste, teaches or suggests a method for repairing a defect locus in a

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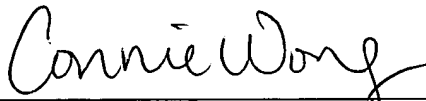
nonarticular cartilage tissue, thereby inducing the formation of functional permanent replacement cartilage tissue to repair the defect, using the specific osteogenic proteins recited in the amended claims. Accordingly, applicants request that the Examiner withdraw this obviousness rejection.

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CONCLUSION

In view of the foregoing remarks and amendments, applicants request that the Examiner favorably reconsider this application and allow the claims pending herein. If the Examiner believes that a telephone conference would expedite allowance of this application, she is invited to telephone the undersigned at any time.

Respectfully submitted,



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